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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,121	01/25/2006	Bruce E. Reidenberg	02755/100J539-US1	3707

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
06/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,121	REIDENBERG ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 3/25/10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al (*Treatment of opioid-dependent pregnant woman with buprenorphine*; Addition (2000) 95(2), 23-244).

The Fischer study teaches a method of treating opioid-dependent pregnant women with a transdermal dosage of buprenorphine (Abstract). The pregnant women were required to be healthy and were administered transmucosal tablets of buprenorphine (page 240 col. 2). Withdrawal symptoms were monitored in the woman as well as neonatal abstinence syndrome in the children upon birth (page 241-page 242). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Granger (EP 0 432 945 hereafter '945) in view of Lintzeris et al (*Buprenorphine dosing regime for inpatient heroin withdrawal: a symptom-triggered dose titration study*, Drug and Alcohol Dependence, 70 (2003) 287-297) and Fischer et al (*Treatment of opioid-dependent pregnant woman with buprenorphine*; Addition (2000) 95(2), 23-244).

The '945 patent discloses a transdermal buprenorphine dosage form comprising from 0.25-100 mg of buprenorphine (abstract, page 2, lin. 49-52). The dosage form results in a blood plasma level from 0.6-6 ng/ml (page 3, lin. 40-48). The transdermal dosage from include all manners of topical and transdermal dosage forms including lotions, gels, sprays, creams, films, and patches (***Ibid.***). The transdermal dosage forms would provide an effective treatment maintaining constant blood levels, effective to reduce withdrawal symptoms of cocaine or heroin addiction. It would have been obvious to dose the patients of the Lintzeris study with the constant stable transdermal formulation of the since the oral and sublingual dosages would only provide immediate relief of symptoms and the transdermal dosage forms would provide prolonged relief and reduce chances of relapse.

Regarding the dosing of the separate dosing periods, the Lintzeris study reports slightly lower concentrations of 4-8 mg being administered. The Lintzeris study teaches a method of treating withdrawal symptoms in heroin addicted patients comprising a titration where the patients were dosed in several separate dosing periods with different concentrations of transdermal buprenorphine formulations (Abstract). The subjects were given a dosage of

buprenorphine on the first day of the trial, 87% of the subjects were given a second dosage the next day, while 62% required further dosing for an additional 3 days (page 390, 3.4). The dosages for the entire 5 day study varied, but in general tapered off as symptoms waned (Table 2 and Fig. 1). The recommended dosing regimen is such that a patient can receive as low as 4 mg of buprenorphine the first day at the onset of withdrawal symptoms and a second dosage of at a separate time of an additional 4 mg. The initial dosing period would be at the onset of symptoms with the second dosing period later that day with the onset of further symptoms. The third dosing period would last for at least the remainder of the five day study with a total of 10 mg of buprenorphine administered (Table 3).

Regarding the plasma concentration of the patient after administration of the third dosing period, it is the position of the Examiner that this limitation is merely functional limitation that would fall naturally from the compositional components of the method. As discussed above the Lintzeris study teaches a dosing regimen describing three separate and distinct dosing periods with the dosage of buprenorphine sublingual tablets, staying the same in the second period and increasing throughout the third period. These disclosures meet the compositional components of the instant claims and as such would meet the functional limitations of the claims.

The combination is silent to the condition of the patient other than their opioid dependency. The use of buprenorphine as a withdrawal treatment for pregnant women is well known in the art as see in the Fischer study. The Fischer study teaches a method of treating opioid-dependent pregnant women with a transdermal dosage of buprenorphine (Abstract). The pregnant women were required to be healthy and were administered transmucosal tablets of buprenorphine (page 240 col. 2). Withdrawal symptoms were monitored in the woman as well

as neonatal abstinence syndrome in the children upon birth (page 241-page 242). It would have been obvious to treat pregnant women with the method of the combination since it can be seen that transdermal buprenorphine treatments are safe and effective for treating withdrawal.

With these things in mind it would have been obvious to combine the device of the '945 with the regimen of the Lintzeris and Fischer studies in order to treat withdrawal safely. It would have been obvious to apply the transdermal buprenorphine of the '945 patent to the proven treatment regimen of the Lintzeris study in order to reduce relapse and maintain symptoms. Further it would have been obvious to transfer this treatment regimen to pregnant women as seen in the Fischer study since it shows that pregnant women can tolerate transdermal buprenorphine regimen. One of ordinary skill in the art would have been motivated to combine the prior art in order to properly and more effectively treat withdrawal symptoms. It would have been obvious to treat withdrawal patients in need thereof as such with an expected result of a treatment regimen that provides improved long term results with reduced incidence of relapse.

Response to Arguments

Applicant's arguments filed 3/25/10 have been fully considered but they are not persuasive. Applicant argues that the Fisher study does not anticipate the instant claims since the study teaches sublingual administration of buprenorphine while the claims recite transdermal administration. However it remains the position of the Examiner that the Fischer study continues to anticipate the instant claims since sublingual administration is a transmucosal delivery method, and transmucosal delivery is recited as a possible transdermal method as recited in claim

15. As such by meeting the limitations of claim 15, the Fischer study continues to anticipate the instant claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Specifically the 103(a) rejection has been amended to include the Fischer study to address the pregnant female limitations as amended. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618